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10/753,715

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/753,715

Applicant(s)

GUNDERSON, RICHARD C.

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-16, 18 and 20-45 is/are pending in the application.
- 4a) Of the above claim(s) 20-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-16, 18, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/4/07, 2/27/07, 4/19/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to the arguments and amendments filed 27 February 2007.

#### ***Drawings***

2. The drawings were received on 27 February. These drawings are accepted.

#### ***Specification***

3. The corrections to the specification have also been accepted.

#### ***Claim Rejections - 35 USC § 112***

4. The 35 U.S.C. § 112 rejections from the previous office action have been withdrawn in view of applicant's remarks on page 13 of 16 of the response.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-3, 8-14, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hebert et al. (2003/0163156).** Hebert et al. (hereinafter Hebert)

reference discloses the delivery system substantially as claimed, including a catheter (24, see figure 3), a sheath (26) with an orifice (64), and a self-expanding stent (28, see paragraph 30) disposed between the catheter (24) and the sheath (26). The member (24) can be considered a catheter because it can be made from either a hypotube or a guidewire (see paragraph 29). When made from a hypotube, the member is interpreted as a catheter. A hypotube is a hollow tubular structure, and a catheter in its broadest sense is simply a hollow tube. The structure is a "catheter" in name only, but a hypotube structure is effectively the same as the structure of a catheter. The orifice is located between the distal end of the sheath and the proximal end of the stent (see figure 3).

7. Regarding claims 2 and 13, there is a plurality of orifices (see figure 3).

8. Regarding claims 3, 14, and 18, the self-expanding endoprosthesis is a stent and the stent has a maximum dimension that is greater than the maximum dimension of the orifice. The maximum dimension of the strut is its length. The length dimension would be greater than the size of the orifice (see figure 3).

9. Regarding claims 8-10 and 12, Hebert reference discloses the uniform cross section of portion 54 has a length of 5 cm (see paragraph 29, lines 16-18), which is 50 mm. As can be seen in figure 3, the distance from the orifice to the distal tip of the sheath falls within that 50 mm length, and therefore the orifice can not be more than 100

mm from the distal end of the sheath. It is also clear that the orifice is more than 1 mm from the end of the sheath.

10. Regarding claim 11, the self-expanding stent can be placed in a lumen of a subject (see figure 6C).

11. **Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Mikus et al. (6,033,413).** Mikus et al. (hereinafter Mikus) reference discloses a guide catheter (10) that guides the inner tubular member (see figure 3). The guide catheter has a plurality of orifices (23) at its distal end (see figures 3 and 4). Mikus reference also discloses the length of the prostatic urethra is 15 to 75 mm (see column 3, line 11). As shown in figure 1, the stent (7) substantially entirely underlies the prostatic urethra. When viewing figure 4, it is clear that the stent entirely covers the orifices. Therefore, the orifices can be no more than 75 mm from a distal end of the guide catheter.

***Claim Rejections - 35 USC § 103***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. **Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hebert et al. (2003/0163156) as applied to claims 1 and 10 above, and further in view of Loeffler (5,891,154).** Hebert reference does not disclose the orifice is sized about 0.02 inches or less. Attention is drawn to Loeffler reference, which teaches orifice sizes may vary as desired (see column 6, lines 37-42) to provide a device that will allow the proper amount of fluid to flow through the device. For example, the perfusion ports

would be larger when used in a larger vessel to provide adequate flow of blood through the device to prevent starving of the vessels and organs that are downstream from the perfusion port. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the perfusion ports of Hebert 0.02 inches, as taught by Loeffler, to provide a device that allows adequate flow of blood through the device to prevent starving of the vessels and organs that are downstream from the perfusion port.

**14. Claims 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hebert et al. (2003/0163156) as applied to claims 1 and 10 above, and further in view of Wilson et al. (6,425,898).** Hebert reference does not disclose the sheath includes multiple layers. Attention is drawn to Wilson et al. reference, which teaches a sheath may have multiple layers with one being a support layer to enhance stent deployment (see column 8, lines 12-19 for specific benefits). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sheath of Hebert reference with multiple layers, as taught by Wilson reference, to enhance stent deployment.

**15. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (6,033,413) as applied to claim 44 above, and further in view of Raeder-Devens et al. (6,726,712).** Mikus reference does not disclose the guide catheter has multiple layers. Attention is drawn to Raeder-Devens et al. reference, which teaches a catheter may have multiple layers (see figure 4 and column 5, lines 30-46) to provide surfaces that provide low friction but also has sufficient strength due to

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the support braid. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the catheter of Mikus with multiple layers, as taught by Raeder-Devens et al. reference, to provide a device with a low friction surface but also has sufficient strength due to the support braid.

### ***Response to Arguments***

16. Applicant's arguments, see the remarks section, pages 15 and 16, filed 27 February 2007, with respect to the rejection(s) of claim(s) 44 and 45 under 35 U.S.C. § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see paragraphs 11 and 15 above).

17. Applicant's amendments of claims 1 and 10 have also raised new grounds of rejection (see above).

### ***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson  
May 2, 2007



**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

5/12/07